

CLAIMS

1. The use of an active agent selected from the group consisting of leptin, leptin fusion proteins, leptin muteins, leptin receptor agonists, active fragments or fractions of any one thereof, active analogs or derivatives of any one thereof, salts of any one thereof, and mixtures of any thereof, as an inhibitor of tumor cell proliferation.

2. The ~~use of an active agent~~ ^{method} according to claim ~~1~~ ²⁸ ~~as an inhibitor of~~ ^{for inhibiting} cell proliferation for the treatment of malignancies in mammals.

3. The ~~use of an active agent~~ ^{method} according to claim ~~1~~ ²⁸ ~~or claim 2~~ ^{for inhibiting} ~~as an inhibitor of~~ growth-factor dependent tumors.

4. The ~~use of an active agent~~ ^{method} according to ~~any one of claims 1-3~~ ^{claims 1-3} ~~as an inhibitor of~~ ^{for inhibiting} human breast carcinoma cell proliferation.

5. The ~~use of an active agent~~ ^{method} according to claim 4 for the treatment of human breast carcinomas.

6. The ~~use of an active agent~~ ^{method} according to claim ~~1~~ ²⁸ ~~or claim 3~~ ^{for inhibiting} ~~as an inhibitor of~~ the growth stimulatory effect of insulin on tumor cells, as mediated, at least partially, by the insulin receptor substrate-1 (IRS-1)/growth-factor receptor-associated binding protein-2 (GRB2) pathway.

7. The ~~use of an active agent~~ ^{method} according to claim ~~1~~ ²⁸ ~~or claim 3~~ ^{for inhibiting} ~~as an inhibitor of~~ the mitogenic responses in tumor cells to one or more receptor kinases, growth factors and cytokines of the group consisting of IGF-1, IL-4 and IL-9, for all of which IRS-1 is a substrate, for the treatment of tumors.

8. The ~~use of an active agent~~ ^{method} according to ~~any one of claims 1-7~~ ^{claim 1} ~~as an inhibitor of~~ ^{for inhibiting} basal and insulin-induced tumor cell proliferation for the treatment of human breast cancers.

a *mb* *cl 7* 9. The ~~use of an active agent~~ ^{method} according to ~~any one of claims 1-8~~ ^{Claim 7} wherein said active ingredient is leptin, and said leptin is used as said inhibitor or for said treatment.

5 10. An active agent selected from the group consisting of leptin, leptin fusion proteins, leptin muteins, leptin receptor agonists, active fragments or fractions of any one thereof, active analogs or derivatives of any one thereof, salts of any one thereof, and mixtures of any thereof, for use in the preparation of a medicament for the inhibition of tumor cell proliferation.

10 11. An active agent according to claim 10 for use in the preparation of a medicament for the treatment of malignancies in mammals.

a 15 12. An active agent according to claim 10 ~~or claim 11~~ for use in the preparation of a medicament for the inhibition of growth-factor-dependent tumors.

a 13. An active agent according to ~~any one of claims 10-12~~ ^{Claim 10} for use in the preparation of a medicament for the inhibition of human breast carcinoma cell proliferation.

20 14. An active agent according to claim 13 for use in the preparation of a medicament for the treatment of human breast carcinomas.

a 25 15. An active agent according to claim 10 ~~or claim 12~~ for use in the preparation of a medicament for the inhibition of the growth stimulatory effect of insulin on tumor cells, as mediated, at least partially, by the IRS-1/GRB2 pathway.

a 30 16. An active agent according to claim 10 ~~or claim 12~~ for use in the preparation of a medicament for the inhibition of the mitogenic responses in tumor cells to one or more receptor kinases, growth factors and cytokines of the group consisting of IGF-1, IL-4 and IL-9, for all of which IRS-1 is a substrate, for the treatment of tumors.

a 17. An active agent according to ^{*claim 10*} ~~any one of claims 10-16~~ for use in the preparation of a medicament for the inhibition of basal and insulin-induced tumor cell proliferation, for the treatment of human breast cancers.

a 5 18. An active agent according to ^{*claim 10*} ~~any one of claims 10-17~~ wherein said active agent is leptin, and said leptin is used for the preparation of said medicament.

a 10 19. A pharmaceutical composition comprising as active ingredient ~~an active agent~~ according to claim 1 ~~or claim 10~~ and a pharmaceutically acceptable carrier, diluent or excipient, for the inhibition of tumor cell proliferation.

20. A pharmaceutical composition according to claim 19 for the treatment of malignancies in mammals.

a 15 21. A pharmaceutical composition according to claim 19 ~~or 20~~ for the inhibition of growth-factor-dependent tumors.

a 20 22. A pharmaceutical composition according to ^{*claim 19*} ~~any one of claims 19-21~~ for the inhibition of human breast carcinoma cell proliferation and thereby for the treatment of human breast carcinoma.

a 25 23. A pharmaceutical composition according to claim 19 ~~or 21~~ for the inhibition of the growth stimulatory effect of insulin on tumor cells, as mediated, at least partially, by the IRS-1/GRB2 pathway.

a 30 24. A pharmaceutical composition according to claim 19 ~~or 21~~ for the inhibition of mitogenic responses in tumor cells to one or more receptor kinases, growth factors and cytokines of the group consisting of IGF-1, IL-4 and IL-9 for all of which IRS-1 is a substrate, and thereby for the treatment of tumors.

25 A pharmaceutical composition according to ~~any one of claims 19-24~~ for the inhibition of basal and insulin-induced tumor cell proliferation and thereby for the treatment of human breast cancers.

5 26. A pharmaceutical composition according to ~~any one of claims 19-25~~ wherein said active ingredient is leptin.

27. A method for treating tumors in mammals or for inhibiting tumor cell proliferation in mammals comprising administering to a patient a pharmaceutical composition according to

10 ~~any one of claims 19-26~~ in a suitable dosage form and by a suitable route of administration.

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